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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,009	09/26/2003	Laurent Schaller	CSI-2027	7654

7590 01/22/2007  
JEFFREY J. HOHENSHELL  
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EXAMINER

NGUYEN, TUAN VAN

ART UNIT PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/672,009		SCHALLER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Tuan V. Nguyen		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 34-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on September 26, 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-33, drawn to an anastomosis device, classified in class 606, subclass 151.
  - II. Claims 34-40, drawn to method of performing an anastomosis, drawn to class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus such as the graft everting apparatus is a separate component with the clip holding and deploying structure.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

2. A telephone call was made to Mr. Jeffery Hohenshell (Reg. No. 34,109) on December 22, 2006 to discuss the above restriction requirement. The result was a provisional election was made without traverse to prosecute the invention of Group

I, claims 1-33. Affirmation of this election must be made by applicant in replying to this Office action. Claims 34-40 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arcia et al. (U.S. 6,358,258) in view of Miller et al. (U.S. 6,709,442).**

6. Referring to claims 1-16, 17-21, 22-30 and 31-33, Arcia discloses (see Figs. 8-12) an anastomosis device 200 comprising: a shaft or support structure 210; one or plurality of Nitinol needles 270 or barb, wherein the needles or barbs slidably

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coupled to the channels or tubular members 240, 250, the needles 270 or barbs are for supporting graft G to the device (see Fig. 11) and for deploying of suture 272 to secure the graft to other vessel; drive tubes 260 coupled to a thumb cap 232, wherein the thumb cap and drive tubes are for simultaneously deploying of flexible needles out of channel 240, 250 or tubular members (see col. 9, line 16 to col. 10, line 48). With respect to **claims 26 and 30**, Arcia discloses the suture 272 is connected to the proximal end of needle 270 and the other end of suture is connected and stored in cap 232, thus, the needle 272 can be retracted into the tubular member 240, 250 if the surgeons desired to do so or if he/she feels that the needle 272 is not deployed to proper location (see col. 9, lines 54-62).

7. Still referring to **claims 1-16, 17-21, 22-30 and 31-33**, However, Miller discloses (see Figs. 5A-5F and 13-34) anastomosis device 50, 170 comprising: a support structure 51, 57 or 226, 218, 220; one or plurality of self-closing clip 10, 236 slidably and disposed in tube 51 or plurality of tube 230 (or first plurality of member), wherein the clips is shape memory clip and the clips assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness (see col. 3, lines 54-60), each clip being releasably coupled to said support structure by plunger 52, 238; a pusher, 60, 210 is connected to plunger 52, 238; and the clips can be deployed simultaneously (see col. 7, line 46 to col. 8, line 40 and col. 12, line 50 to col. 13, line 25).

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8. Still referring to claims **1-16, 17-21, 22-30 and 31-33**, therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to incorporate the device of Miller for delivery the clip or clips independently from the barb or barbs into the device, as disclosed by Arcia in order to gain the advantages of using shape memory clip wherein after the fastener or clip is deployed through layers of tissue the clips assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness, the fastener or clip is a suitable replacement for conventional non bio-absorbable sutures and staples in certain clinical application as suggested by Miller (see col. 3, lines 54-64) while the graft holding technique of Arcia still maintain because it is more superior than the graft holding technique of Miller.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen  
January 8, 2006

  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER  
1/12/07.